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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,196	04/13/2001	Barnett S. Pitzele	PHAR 7979/3313US	5348

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EXAMINER

ZUCKER, PAUL A

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 07/16/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/835,196

Applicant(s)

PITZELE ET AL.

Examiner

Paul A. Zucker

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Specification***

1. The abstract of the disclosure is objected to because it does not set forth what the contribution to the art the disclosure makes. The abstract should describe the structural class of the compounds or include a structural diagram. A revised abstract on a separate sheet is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 28 is rendered indefinite because of the following: A position designator (number) for the amino group appears to be missing from all but the 1<sup>st</sup> and 9<sup>th</sup> listed compounds. It is therefore impossible to determine the scope of Applicant's claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

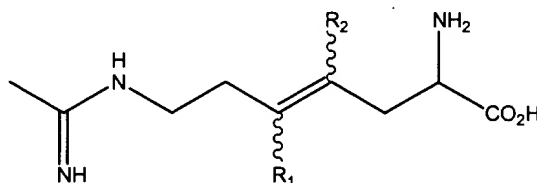
(1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

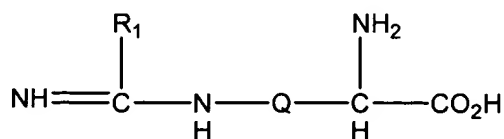
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beams et al (WO 93/13055-A1 07-1993).

The instantly claimed invention is directed toward the compounds (geometric and stereoisomers) of Formula (I), where  $R_1$  and  $R_2$  may be H or methyl, or their pharmaceutically acceptable salts :



Beams teaches (Page 5, line 26-page 7, line 35) a genus of nitric oxide synthase inhibitors of general formula (I):



Where  $R^1$  may be a  $C_{1-6}$  straight chain or branched alkyl and Q may be an alkylene, alkenylene or alkynylene group having 3-6 carbons. Beams further teaches (Page 5, line 37-page 6, line 1) optional substitution of Q by one or more  $C_{1-3}$  alkyl groups. A

preferred embodiment of the compounds is further taught (Page 6 lines 30-36) where  $Q = -(CH_2)_vCH=CH(CH_2)_w-$  where  $v = 0-3$ ;  $w = 0$  to  $3$ ; and  $v + w = 2-4$ . The instantly claimed compounds correspond to  $v = 2$ ,  $w = 1$  and thus fall within the narrow subgenus suggested by Beams. Beams further teaches (Page 7, lines 1-3) a preferred value for  $R^1$  of methyl. Beams further teaches (Page 3, lines 23-34) that the genus encompasses all stereoisomeric forms (both E,Z and R,S).

Beams teaches (Page 8, line 14 – page 11, line 4) pharmaceutical compositions of the compounds as well. Beams further teaches (Page 16, lines 15 – 25) methods for the selective inhibition of the inducible form of nitric oxide synthase using the compounds of his invention.

Instant claim 28 (1<sup>st</sup> and 2<sup>nd</sup> listed compounds) is obvious over Beams' exemplification (Page 15, lines 1-10, Example 8) of (±)-Z-2-Amino-6-(1-iminoethylamino)-hex-4-enoic acid, hydrochloride. The 1<sup>st</sup> and 2<sup>nd</sup> listed compounds of claim 28 are simply the salts of the adjacent higher homologue with one additional chain methylene unit between the double bond and the amidino group. One of ordinary skill in the art would have the expectation of similar properties for the instant compounds and that of Beams and the instant compounds are therefore obvious over that of beams.

Thus the instantly claimed compounds, pharmaceutical compositions containing them and the instantly claimed method of use would have been obvious to one of ordinary skill in the art. The motivation for the instantly claimed invention would have

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been to develop other compounds in the genus taught by Beams and apply them, in the compositions taught by Beams, to the methods taught by Beams. The expectation for success would have been near certitude since Beams' genus completely embraces the instant compounds which, Beams' teaches, have the instantly desired activity as nitric oxide synthase inhibitors.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 09/834,815. Although the conflicting claims are not

identical, they are not patentably distinct from each other because the instantly claimed compounds simply represent isomers of the compounds of 09/834,815 in which the double bond position has been shifted one carbon closer to the stereogenic carbon bearing both the carboxyl and amino groups. Because of the close structural relationship of the instantly claimed compounds and their common utility with those of 09/834,815 there would be strong expectation of similar results by one of ordinary skill in the art. In the absence of a showing of surprising results, the instant compounds are obvious over those of 09/834,815.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

5. Claims 1-31 are outstanding. Claims 1-31 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are

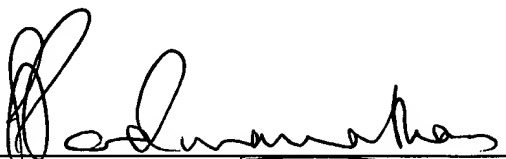
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703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Paul A. Zucker  
Patent Examiner  
Technology Center 1600

July 15, 2002

(for)   
Johann Richter, Ph.D., Esq.  
Supervisory Patent Examiner  
Technology Center 1600 7/15/02